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SANUWAVE Health Receives Full Approval From the FDA to Conduct the dermaPACE Pivotal Clinical Trial

- **FDA has approved clinical study design**
- **15 Clinical site contracts negotiated**
- **First enrollment anticipated in Q2-2013**
- **CPC Clinical Research engaged as CRO**

ALPHARETTA, Ga., March 13, 2013 (GLOBE NEWSWIRE) -- **SANUWAVE Health, Inc.** (OTCBB:SNWV) today provided an update on the Company's clinical trial investigating the dermaPACE® device in the treatment of diabetic foot ulcers.

The U.S. Food and Drug Administration (FDA) has granted full approval of the Company's Investigational Device Exemption (IDE) Supplement to conduct a clinical trial utilizing the dermaPACE device in the treatment of diabetic foot ulcers. This clinical trial provides a scientifically robust and expeditious pathway to a Premarket Approval (PMA) submission to the FDA for their review and consideration of device approval.

"The dermaPACE study design was built off of the positive treatment effect observed in the first study. This study includes several important features which greatly increase the probability of the clinical study's success," stated Mr. Joseph Chiarelli, Chief Executive Officer of SANUWAVE. "These features include:

- **Doubling the number of patient treatments** - Similar to the previous trial, four (4) dermaPACE procedures will be administered during the first two weeks. In addition, in the upcoming trial, up to four (4) additional dermaPACE procedures will be delivered bi-weekly, between weeks 4 and 10. We believe these additional treatments will increase the between-group difference in complete wound closure in favor of dermaPACE over that observed in the first clinical trial.
- **Credit for the positive treatment effect observed in the previous trial**- The study uses Bayesian statistical principles, which statistically credits the dermaPACE group at the start of this trial with the positive treatment effect observed in the previous trial. This design also allows for fewer patients than would be enrolled in a standard trial design, with study success potentially occurring with as few as ninety (90) patients.
- **Interim monitoring of the data by an independent Data Monitoring Committee (DMC)** to determine whether study success has been achieved. This provision has been established in order to monitor the progress of the trial, and ensure its alignment with our statistical plan. The first analysis for making a study success determination is projected to occur after 90 patients (approximately 45 per arm) have completed the 12-week primary efficacy evaluation period.

- **Centralized review of digital wound pictures** – In addition to the determination of wound closure by each study site's Principal Investigator, an independent group of medical professionals will also assess wound closure. This will provide consistency in determining when a wound is classified as closed. This independent review of wound closure will be performed with the use of a state-of-the-art, digital, wound imaging system.
- **Standardized wound debridement** guidelines to ensure wounds are debrided aggressively early and then less vigorously as the wounds heal. This will provide consistency among sites in how debridement is performed.

In addition, we have strengthened our internal team with the addition of Joel Batts, Vice President of Clinical Affairs, who will manage the execution of the trial. Joel joined us in October 2011 and has over 13 years of IDE trial experience. He was one of the key architects in designing the new trial.

We have already negotiated contracts with 15 clinical study sites and are in the final stages of qualifying and contracting additional sites to reach our goal of 20 sites by the time of enrollment of the first patient. Patient enrollment is expected to begin in the second quarter of this year. We believe the clinical trial could be completed and the data from the clinical trial available for review in support of a Premarket Approval (PMA) application for dermaPACE as early as the end of 2014, assuming such data to be collected meets the agreed upon statistical and clinical plan of success."

The Company has contracted with CPC Clinical Research (CPC) for database design and management, site monitoring, and core lab services for the dermaPACE clinical trial.

"CPC is pleased to be selected to collaborate with the team at SANUWAVE," said William R. Hiatt, MD, President of CPC and Professor of Medicine at the University of Colorado. "We are primed to apply our industry-leading resources and experiences in wound healing and quality control to the study of diabetic foot ulcers treated with the dermaPACE device."

Mr. Chiarelli concluded, "I'm pleased to announce this collaboration with CPC, a world leading academic clinical research organization, as we move from the planning phase into the execution phase of our dermaPACE clinical trial. The dermaPACE treatment addresses a large, unmet medical need. We remain focused on achieving FDA approval as soon as possible in order to make dermaPACE available to the millions of U.S. patients who suffer from this debilitating, recalcitrant problem."

dermaPACE Phase III Clinical Study Design
SANUWAVE expects to enroll a minimum of 90 patients into the dermaPACE Phase III clinical trial (~45 in the treatment arm and ~45 in the control arm) in 20 sites in the U.S. The clinical study is a prospective, randomized, double-blinded, multicenter, 24-week, parallel group study.

Patients will receive four (4) non-invasive procedures (dermaPACE or control) during the first two weeks. In addition, up to four (4) additional non-invasive procedures (dermaPACE or control) will be delivered bi-weekly, between weeks 4 and 10. The patients will be followed 12 weeks for efficacy and an additional 12 weeks for safety.

The goal of the trial is to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment as compared the control group, when both are combined with wet-to-dry dressings and, for some patients, offloading with a walking boot. Secondary trial endpoints included time to closure, reduction in total wound surface area and volume, rate of recurrence and safety assessments. The study's primary endpoint of wound closure is defined as full skin reepithelialization without drainage or dressing requirements confirmed at two consecutive visits.

About SANUWAVE Health, Inc.
SANUWAVE Health, Inc. (www.sanuwave.com) is a shock wave technology company initially focused on the development and commercialization of noninvasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. SANUWAVE's portfolio of regenerative medicine products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. SANUWAVE intends to apply its PACE technology in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions. Its lead product candidate for the global wound care market, dermaPACE, is CE Marked and has Canadian device license approval for the treatment of the skin and subcutaneous soft tissue. In the U.S., dermaPACE is currently under the FDA's Premarket Approval (PMA) review process for the treatment of diabetic foot ulcers. SANUWAVE researches, designs, manufactures, markets and services its products worldwide, and believes it has demonstrated that its technology is safe and effective in stimulating healing in chronic conditions of the foot (plantar fasciitis) and the elbow (lateral epicondylitis) through its U.S. Class III PMA approved Ossatron® device, as well as stimulating bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of its Ossatron, Evotron® and orthoPACE® devices in Europe and Asia.

About CPC Clinical Research
Founded in 1989 by the University of Colorado, CPC Clinical Research is a non-profit, academically led Clinical Research Organization (CRO) that has responded to the demands of a fast-paced clinical research industry and competitive market for over two decades. Led by William Hiatt, MD, CPC has provided clinical trial design, oversight, and management services to over 140 clinical trials across all phases and covering a variety of indications, including wound, cardiovascular, diabetes, asthma, vaccines, and oncology. Dr. Hiatt is a past Chair of the FDA Cardiovascular and Renal Advisory Committee (2003-08) and currently serves on the Endocrinologic and Metabolic Drugs Advisory Committee. In addition, Dr. Hiatt is the Novartis Foundation endowed professor for cardiovascular research in the Department of Medicine, Division of Cardiology, University of Colorado School of Medicine. For more information on CPC: www.cpcmed.org

Forward-Looking Statements
This press release may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements relating to financial results and plans for future business development activities, and are thus prospective. Forward-looking statements include all statements that are not statements of historical fact regarding intent, belief or current expectations of the Company, its directors or its

officers. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, many of which are beyond the Company's ability to control. Actual results may differ materially from those projected in the forward-looking statements. Among the key risks, assumptions and factors that may affect operating results, performance and financial condition are risks associated with the regulatory approval and marketing of the Company's product candidates and products, unproven pre-clinical and clinical development activities, regulatory oversight, the Company's ability to manage its capital resource issues, competition, and the other factors discussed in detail in the Company's periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statement.

For additional information about the Company, visitwww.sanuwave.com.

CONTACT: DC Consulting, LLC
407-792-3333
investorinfo@dcconsultingllc.com

SANUWAVE Health, Inc.
Barry Jenkins, 678-578-0103
Chief Financial Officer and COO
investorrelations@sanuwave.com

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